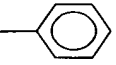
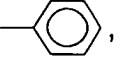


G<sup>2</sup>  
--9. A corticoid 17,21-dicarboxylic ester or corticosteroid 17-carboxylic ester 21-carbonic ester of the formula I as claimed in claim 1, wherein A is CHOH, Y is hydrogen, Z is hydrogen, (C<sub>1</sub>-C<sub>4</sub>)-alkyl is C<sub>1</sub>-alkyl, R(1) is unsubstituted phenyl, R(2) is , and R(3) is hydrogen.

10. A corticoid 17,21-dicarboxylic ester or corticosteroid 17-carboxylic ester 21-carbonic ester of the formula I as claimed in claim 1, wherein A is CHOH, Y is fluorine, Z is hydrogen, (C<sub>1</sub>-C<sub>4</sub>)-alkyl is C<sub>1</sub>-alkyl, R(1) is unsubstituted phenyl, R(2) is , and R(3) is β-methyl.--

### REMARKS

#### **I. Claims Pending**

Claims 1, 3-5, and 7-10 are pending in this application. New claims 9-10 cover the compounds prednisolone 17-benzoate 21-phenylacetate and betamethasone 17-benzoate 21-phenylacetate, respectively. Support for claims 9 and 10 appears in Examples 23 and 59 of the specification. This amendment does not raise new issues or necessitate any additional search of the art by the Examiner. Claim 7 has been amended to include a definition of R(2) that was present in original claim 7 but was inadvertently omitted from claim 7 as amended on September 15, 1998. Claims 9 and 10 are species of claim 1 and should be allowable when the Examiner finds claim 1 allowable.

#### **II. Rejection of Claim 7 Under 35 U.S.C. § 112, Second Paragraph**

The Examiner rejected claim 7 under 35 U.S.C. § 112, second paragraph, as incomplete because it lacks a definition of R(2). The Examiner also noted that claim 7 does not end with a period. Claim 7 has been amended to correct the deficiencies noted by the Examiner, and the rejection should therefore be withdrawn.

**III. Rejection of Claims 1, 4-5, and 7 Under 35 U.S.C. § 103(a)**

The Examiner maintained the rejection of claims 1, 4-5, and 7 under 35 U.S.C. § 103(a) over Page et al. The rejection is respectfully traversed.

**A. The Prior Art Must Motivate One Skilled in the Art to Select the Claimed Compounds from the Page et al. Disclosure.**

The Examiner argued that the compounds of claim 1 are encompassed by the genus of compounds disclosed in Page et al. As the Examiner is aware, "[t]he fact that a claimed species *or subgenus* is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness." M.P.E.P. § 2144.08(II) (emphasis added). Instead, "[s]ome motivation to select the claimed species *or subgenus* must be taught by the prior art." M.P.E.P. § 2144.08(II)(A)(4)(a) (emphasis added).

The Patent and Trademark Office has prescribed Interim Guidelines in M.P.E.P. § 2144.08 ("Guidelines") for evaluating whether a single prior art reference disclosing a genus may render obvious a particular species or subgenus of that reference's disclosure. The Guidelines rely on a number of decisions cited by the applicants, including In re Baird, 29 U.S.P.Q.2d 1550 (Fed. Cir. 1994), and In re Jones, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992). In the instant Office action, the Examiner argued that In re Baird was not applicable to the present case, contending that the pending claims encompass numerous compounds, and the claim on appeal in Baird was directed only to a specific compound. The Guidelines, however, rely on In re Baird in formulating the examination procedures for determining the obviousness of either a single species *or a subgenus* of a prior art disclosure. The Examiner's interpretation of In re Baird as applicable only to claims directed to a single species compound therefore is at odds with the interpretation of In re Baird given by the Patent and Trademark Office Guidelines. Applicants should therefore be entitled to rely on the reasoning of In re Baird that is applied below.

**B. Page et al. Does Not Motivate One Skilled in the Art to Select the Claimed Compounds from the Page et al. Disclosure.**

In determining whether one skilled in the art would be motivated to select a subgenus from a prior art genus, the Guidelines require that the Examiner consider, *inter alia*, the number of variables that must be selected or modified in the genus to arrive at the claimed subgenus, any express teachings to select the claimed subgenus, and any species or subgenus that is specifically disclosed within the prior art genus.

The number of variables that must be selected simultaneously to arrive at the claimed compounds from the Page et al. disclosure is very high. For example, the 21-side chain of the invention is -O-CO-[(C<sub>1</sub>-C<sub>4</sub>)-alkyl]-phenyl, with the phenyl being unsubstituted or substituted by one of the radicals recited in claim 1. In order to approximate this side chain, R<sub>5</sub> of Page et al. must be defined as R<sub>6</sub>, R<sub>6</sub> must be defined as OR<sub>7</sub>, where R<sub>7</sub> is defined as an acyl group of the formula R'CO, and R' must be defined as an aralkyl group of 7 to 8 carbon atoms. In addition to matching the 21-position side chain, the compounds of claim 1 recite substituents including A, Z, and R(2) that must be matched by selectively and simultaneously choosing specific variables from Page et al.'s generic disclosure.

There is no teaching or suggestion in Page et al. to follow the paths taken by the applicants. Indeed, no specific examples in Page et al. even include a phenyl group in the 21-position side chain as claimed. The present situation is therefore analogous to that in In re Jones, 21 U.S.P.Q.2d at 1994, where the court reversed the Patent and Trademark Office's finding of obviousness because there was no motivation shown to select the claimed species from the prior art genus:

Conspicuously missing from this record is any evidence, other than the PTO's speculation (if it be called evidence) that one of ordinary skill in the herbicidal art would have been motivated to make the modifications of the prior art salts necessary to arrive at the claimed [compound].  
(Emphasis in original).

Examples 9 and 19, specifically cited by the Examiner, likewise fail to motivate one skilled in the art to derive the claimed compounds. The Examiner even acknowledges that the radicals at the 21-position of examples 9 and 19 are hydroxyl or acetate groups, not the required -O-CO-[(C<sub>1</sub>-C<sub>4</sub>)-alkyl]-phenyl group. In fact, all of the reference examples refer to aliphatic group substituents in the 21-position, and the lack of motivation to arrive at the claimed compounds renders the rejection improper. See In re Lulu, 223 U.S.P.Q. 1257, 1258 (Fed. Cir. 1984) ("The prior art must provide one of ordinary skill in the art the motivation to make the proposed molecular modifications needed to arrive at the claimed compounds.").

The Examiner argues that motivation to derive applicants' compounds may be found in Page et al. because "the reference teaches an equivalence between hydroxyl and an acyloxy group (i.e., acyloxy groups having either an alkyl or an aralkyl moiety) at the 21-position." This argument, however, is contradicted by the reasoning of In re Baird. Following In re Baird, Page et al.'s emphasis on the dissimilar aliphatic 21-position substituents in the disclosed examples, including Examples 9 and 19, actually acts as a teaching away from the present invention, not a teaching of equivalency:

While the Knapp formula unquestionably encompasses bisphenol A when specific variables are chosen, there is nothing in the disclosure of Knapp suggesting that one should select such variables. Indeed, Knapp appears to teach away from the selection of bisphenol A by focusing on more complex diphenols . . . .

In re Baird, 29 U.S.P.Q.2d at 1552.

In sum, the claimed compounds may only be approximated from a complex hindsight selection of specific substituents in formula I of the Page et al. reference. Such hindsight construction of the claimed compounds may not form the basis of this rejection. See In re Fritch, 23 U.S.P.Q.2d 1780, 1784 (Fed. Cir. 1992) ("It is impermissible to use the claimed invention as an instruction manual or 'template' to

piece together the teachings of the prior art so that the claimed invention is rendered obvious." ). The rejection is therefore in error and should be withdrawn.

**IV. Clarification of Rejection of Claims 1-2 and 4-5 Over Annen ('763)**

In the Office action dated November 19, 1997, the Examiner rejected claims 1-2 and 4-5 under 35 U.S.C. § 103(a) over Annen et al. ('763) (See item 15 of the Office action). In subsequent Office actions dated June 16, 1998, and November 5, 1998, the Examiner neither explicitly withdrew nor maintained that rejection. Applicants therefore assume that the rejection was withdrawn. Confirmation is respectfully requested.

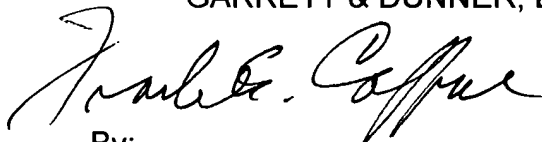
**CONCLUSION**

In view of the foregoing, it is urged that the pending claims are in condition for allowance. An early and favorable action is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this response, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

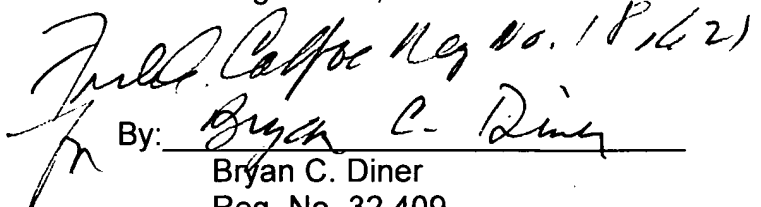
FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.



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Frank E. Caffoe

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By: \_\_\_\_\_

Bryan C. Diner

Reg. No. 32,409

Date: March 1, 1999